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15 Attorneys for Plaintiff

16 IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

17 IN AND FOR THE COUNTY OF PIMA

18 STATE OF ARIZONA, *ex rel.* THOMAS C.
19 HORNE, Attorney General,

No. C20143053

20 Plaintiff

JOINT MOTION TO ENTER
CONSENT JUDGMENT

21 vs.

22 GLAXOSMITHKLINE LLC,

JAMES MARNER

23 Defendant.

24 The parties, by and through undersigned counsel, respectfully move this Court
25 to enter an Order Re: Consent Judgment in the above-entitled action, a copy of which
26 Order is filed contemporaneously with this Motion as Exhibit A.

27 THOMAS C. HORNE
28 ATTORNEY GENERAL

FOR DEFENDANT GLAXOSMITHKLINE LLC

29 By: Noreen R. Matts, Stephen Emedi
30 Noreen R. Matts
31 Stephen Emedi
32 Attorneys for Plaintiff

33 By: Matthew J. O'Connor
34 Matthew J. O'Connor
35 Covington & Burling LLP
36 1201 Pennsylvania Avenue, NW
37 Washington, DC 20004-2401

38 Date: 6/2/2014

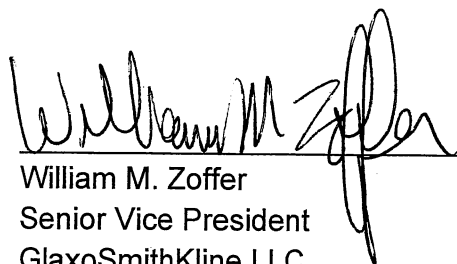
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APPROVED:

FOR DEFENDANT GLAXOSMITHKLINE LLC

By:



William M. Zoffer
Senior Vice President
GlaxoSmithKline LLC

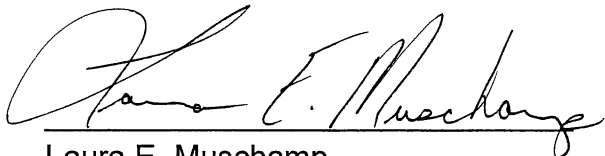
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APPROVED AS TO FORM:

FOR DEFENDANT GLAXOSMITHKLINE LLC

By:  5-19-14 Date

Laura E. Muschamp
Arizona Bar No.017531
Covington & Burling LLP
9191 Towne Centre Drive, 6th Floor
San Diego, CA 92122-1225
Local Counsel for GlaxoSmithKline LLC

EXHIBIT A

1 Thomas C. Horne
2 Attorney General
3 Firm Bar No. 14000
4 Noreen R. Matts
5 Assistant Attorney General
6 State Bar No. #010363
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15 Attorneys for Plaintiff

16 **IN THE SUPERIOR COURT OF THE STATE OF ARIZONA**

17 **IN AND FOR THE COUNTY OF PIMA**

18 STATE OF ARIZONA, *ex rel.* THOMAS C.
19 HORNE, Attorney General,

No. _____

20 Plaintiff

ORDER RE: CONSENT JUDGMENT

21 vs.

22 GLAXOSMITHKLINE LLC,

23 Defendant.

24 The above-listed parties, by and through undersigned counsel, have filed a
25 Joint Motion to Enter Consent Judgment, a copy of which is filed contemporaneously
26 with this Order. Based on the above-listed parties' Joint Motion to Enter Consent
27 Judgment and good cause appearing,

28 **THE COURT HEREBY FINDS AND ORDERS:**

1. The State of Arizona filed a Complaint alleging violations of A.R.S. § 44-
1521 *et seq.*, the Consumer Fraud Act, against defendant GLAXOSMITHKLINE LLC.

2. The State of Arizona, by its counsel, and GLAXOSMITHKLINE LLC, by
their counsel, have agreed to the entry of this Order by the Court without trial or

1 adjudication of any issue of fact or law, and without admission of wrongdoing or liability
2 of any kind.

3 3. The terms of the Consent Judgment ("Judgment") shall be governed by
4 the laws of the State of Arizona.

5 4. The Superior Court has jurisdiction to enter appropriate orders pursuant
6 to A.R.S. § 44-1528.

7 5. Venue is proper in Pima County, Arizona.

8 **I. DEFINITIONS**

9 The following definitions shall be used in construing this Consent Judgment:

10 1. "Applicable Clinical Trials" shall mean those clinical trials required by the FDA
11 Amendments Act of 2007 (Public Law No. 110-85).

12 2. "Attorneys General" shall mean the Attorneys General of the Multistate Working
13 Group.

14 3. "Clinically Relevant Information" shall mean information that reasonably prudent
15 clinicians would consider relevant when making prescribing decisions regarding a GSK
16 Product.

17 4. "Clinical Response" shall mean a non-Promotional, scientific communication to
18 address Unsolicited Requests for medical information.

19 5. "Covered Conduct" shall mean GSK's Promotional practices, dissemination of
20 information, and remuneration to HCPs regarding the prescription drugs Advair®,
21 Paxil®, and Wellbutrin® in the United States.

22 6. "Effective Date" shall mean the date on which a copy of this Consent Judgment,
23 duly executed by GSK and by the signatory Attorney General, is approved by, and
24 becomes a Judgment, of the Court.

25 7. "GlaxoSmithKline LLC," "GlaxoSmithKline," or "GSK" shall mean
26 GlaxoSmithKline LLC, including all of its predecessors, subsidiaries, successors, and
27 assigns.

28

1 8. "GSK Law Department" shall mean personnel of the GSK Law Department or
2 its designee providing legal advice to GSK.

3 9. "GSK Marketing" shall mean GSK personnel responsible for marketing GSK
4 Products.

5 10. "GSK Medical Affairs" shall mean the organization within GSK consisting of
6 highly trained experts with specialized scientific and medical knowledge, usually with
7 an advanced scientific degree (e.g., an MD, PhD, or PharmD), whose role is limited to
8 the provision of specialized, medical or scientific information, scientific analysis and/or
9 scientific information to HCPs but excludes anyone performing sales, marketing,
10 Promotional ride alongs, or other primarily commercial roles.

11 11. "GSK Product" or "GSK Products" shall mean: (1) Advair®; (2) Paxil®; (3)
12 Wellbutrin®; (4) any pharmaceutical or biological product approved by the Food and
13 Drug Administration for the treatment of major depressive disorder; (5) any selective
14 serotonin reuptake inhibitor (SSRI); and (6) any norepinephrine dopamine reuptake
15 inhibitor (NDRI), that GSK Promotes or for which it directs Promotion.

16 12. "GSK Sales" shall mean the GSK sales force responsible for selling GSK
17 Products.

18 13. "GSK Scientifically Trained Personnel" shall mean GSK personnel who are
19 highly trained experts with specialized scientific and medical knowledge, usually with
20 an advanced scientific degree (e.g., an MD, PhD, or PharmD), whose roles involve the
21 provision of specialized, medical or scientific information, scientific analysis and/or
22 scientific information to HCPs but excludes anyone performing sales, marketing,
23 Promotional ride alongs, or other primarily commercial roles.

24 14. "Health Care Professional" or "HCP" shall mean any physician or other health
25 care practitioner who is licensed to provide health care services or to prescribe
26 pharmaceutical products.

27 15. "Meta-analyses" shall mean formal analyses combining evidence from
28 independent studies using appropriate statistical methods, but shall not include any

1 such analyses conducted in connection with the preparation or submission of an
2 Investigational New Drug Application (IND), New Drug Application (NDA),
3 Supplemental New Drug Application (sNDA), Abbreviated New Drug Application,
4 (ANDA), nor shall it include any such analyses conducted in connection with any other
5 regulatory report required under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et
6 seq. (FDCA), or by the U.S. Food and Drug Administration (FDA) or other regulatory
7 body, to the extent the content or submission of which is treated as non-public or
8 confidential by the relevant agency.

9 16. "Multistate Executive Committee" shall mean the Attorneys General and their
10 staff representing Arizona, Florida, Illinois, Maryland, Oregon, Pennsylvania,
11 Tennessee, and Texas.

12 17. "Multistate Working Group" shall mean the Attorneys General and their staff
13 representing Alabama, Arizona, Arkansas, California, Colorado, Connecticut,
14 Delaware, the District of Columbia, Florida, Georgia¹, Hawaii², Idaho, Illinois, Indiana,
15 Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota,
16 Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North
17 Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South
18 Dakota, Tennessee, Texas, Utah³, Vermont, Virginia, Washington, Wisconsin, and
19 Wyoming.

20 _____
21 ¹ With regard to Georgia, the Administrator of the Fair Business Practices Act, appointed pursuant to
22 O.C.G.A. § 10-1-395, is statutorily authorized to undertake consumer protection functions for the State of
23 Georgia. References to the "States," "Parties," or "Attorneys General," with respect to Georgia, include
24 the Administrator of the Fair Business Practices Act.

25 ² Hawaii is being represented on this matter by its Office of Consumer Protection, an agency which is
26 not part of the state Attorney General's Office, but which is statutorily authorized to undertake consumer
27 protection functions, including legal representation of the State of Hawaii. For simplicity, the entire
28 group will be referred to as the "Attorneys General," and such designation, as it includes Hawaii, refers
to the Executive Director of the State of Hawaii Office of Consumer Protection.

³ The Utah Attorney General's Office represents the Utah Division of Consumer Protection (Division),
the state agency charged with enforcement of the Consumer Sales Practices Act, in this action, but is
not a party itself. As to Utah, the definition of "Attorneys General" means the Utah Attorney General as
counsel to the Division.

1 18. "Off-Label" shall mean a non-FDA approved use.

2 19. "Parties" shall mean the Arizona Attorney General and GSK.

3 20. "Promotional," "Promoting," or "Promote" shall mean representations about a
4 GSK Product intended to influence sales of that product, including attempts to
5 influence prescribing practices and utilization of a GSK Product, that would be deemed
6 Promotional labeling or advertising under the FDCA or any regulation promulgated
7 thereunder, or by the FDA, under the most current draft or final standard promulgated
8 by the FDA or the most current draft or final FDA Guidance for Industry.

9 21. "Promotional Materials" shall mean any item used to Promote any GSK
10 Product.

11 22. "Relevant State Consumer Protection Statutes" shall mean the consumer
12 protection laws under which the Attorneys General have conducted the investigation.⁴

13 23. "Reprints Containing Off-Label Information" shall mean articles or reprints from
14 a Scientific or Medical Journal, as defined in 21 C.F.R. 99.3(j), or Reference
15 Publication, as defined in 21 C.F.R. 99.3(i), describing an Off-Label use of a GSK
16 Product.

17 24. "Unsolicited Request" shall mean a request for information regarding a GSK
18 Product communicated to an agent of GSK that has not been prompted by GSK.

19 II. FINDINGS

20 1. This Court has jurisdiction over the subject matter of this lawsuit and over all
21 Parties.

22 2. The terms of this Consent Judgment shall be governed by the laws of the State
23 of Arizona.

24 3. Entry of this Consent Judgment is in the public interest and reflects a negotiated
25 agreement among the Parties.

26

27

28 ⁴ In Arizona, the relevant state statute is The Consumer Fraud Act, A.R.S. § 44-1521 *et seq.*

1 4. GlaxoSmithKline, at all times relevant hereto, engaged in trade and commerce
2 affecting consumers, within the meaning of the The Consumer Fraud Act, A.R.S. § 44-
3 1521 et seq. in the State of Arizona, including, but not limited to, Pima County.

4 5. The Attorneys General conducted an investigation regarding the Covered
5 Conduct. The Parties have agreed to resolve the concerns related to the Covered
6 Conduct under the Relevant State Consumer Protection Laws by entering into this
7 Consent Judgment. This Consent Judgment reflects a negotiated agreement entered
8 into by the Parties as their own free and voluntary act, and with full knowledge and
9 understanding of the nature of the proceedings and the obligations and duties imposed
10 by this Consent Judgment. GSK is entering into this Consent Judgment solely for the
11 purpose of settlement, and nothing contained herein may be taken as or construed to
12 be an admission or concession of any violation of law or regulation, or of any other
13 matter of fact or law, or of any liability or wrongdoing, all of which GSK expressly
14 denies. Through this Consent Judgment, GSK does not admit any violation of law,
15 and does not admit any wrongdoing that was or could have been alleged by any of the
16 signatory Attorneys General before the date of the Consent Judgment. No part of this
17 Consent Judgment, including its statements and commitments, shall constitute
18 evidence of any liability, fault, or wrongdoing by GSK. This Consent Judgment does
19 not constitute an admission by GSK that the Covered Conduct violated or could violate
20 the Relevant State Consumer Protection Laws. It is the intent of the Parties that this
21 Consent Judgment shall not be admissible or binding in any other matter, including,
22 but not limited to, any investigation or litigation, other than in connection with the
23 enforcement of this Consent Judgment. No part of this Consent Judgment shall create
24 a private cause of action or convert any right to any third party for violation of any
25 federal or state statute or law, except that an Attorney General may file an action to
26 enforce the terms of this Consent Judgment. Nothing contained herein prevents or
27 prohibits the use of this Consent Judgment for purposes of enforcement by the
28 Arizona Attorney General.

1 6. This Consent Judgment does not create a waiver or limit GSK's legal rights,
2 remedies, or defenses in any other action by the Arizona Attorney General, and does
3 not waive or limit GSK's right to defend itself from, or make arguments in, any other
4 matter, claim, or suit, including, but not limited to, any investigation or litigation relating
5 to the existence, subject matter, or terms of this Consent Judgment. Nothing in this
6 Consent Judgment shall waive, release, or otherwise affect any claims, defenses, or
7 other positions GSK may assert in connection with any investigations, claims, or other
8 matters the Attorneys General are not releasing hereunder. Notwithstanding the
9 foregoing, the Arizona Attorney General may file an action to enforce the terms of this
10 Consent Judgment.

11 7. This Consent Judgment does not constitute an approval by the Attorneys
12 General of GSK's business practices, and GSK shall make no representation or claim
13 to the contrary.

14 8. This Consent Judgment sets forth the entire agreement between the Parties
15 hereto and supersedes all prior agreements or understandings, whether written or oral,
16 between the Parties and/or their respective counsel, with respect to the Covered
17 Conduct.

18 9. This Court retains jurisdiction of this Consent Judgment and the Parties hereto
19 for the purpose of enforcing and modifying this Consent Judgment and for the purpose
20 of granting such additional relief as may be necessary and appropriate.

21 10. This Consent Judgment may be executed in counterparts, each of which shall
22 be deemed to constitute an original counterpart hereof, and all of which shall together
23 constitute one and the same Consent Judgment. One or more counterparts of this
24 Consent Judgment may be delivered by facsimile or electronic transmission with the
25 intent that it, or they, shall constitute an original counterpart hereof.

26 11. This Consent Judgment relates solely to GSK's business in the United States.

27 12. This Consent Judgment (or any portion thereof) shall in no way be construed to
28 prohibit GSK from making representations with respect to any GSK Product that are

1 permitted under Federal law or labeling for the drug under the most current draft or
2 final standard promulgated by the FDA or the most current draft or final FDA Guidance
3 for Industry, or permitted or required under any IND, NDA, sNDA, or ANDA approved
4 by the FDA, so long as the representation, taken in its entirety, is not false, misleading
5 or deceptive.

6 13. Nothing in this Judgment shall require GSK to:

7 a) take any action that is prohibited by the FDCA or any regulation
8 promulgated thereunder, or by the FDA; or

9 b) fail to take any action that is required by the FDCA or any regulation
10 promulgated thereunder, or by the FDA;

11 or shall preclude GSK from providing health care economic information to a formulary
12 committee or similar entity or its members in the course of the committee or entity
13 carrying out its responsibilities for the selection of drugs for managed care or other
14 similar organizations pursuant to the standards of Section 114 of the Food and Drug
15 Administration Modernization Act of 1997 (FDAMA), if the information directly relates
16 to an approved indication of a GSK Product, and if based on competent and reliable
17 scientific evidence.

18 III. COMPLIANCE PROVISIONS

19 Promotional Activities

20 A. GSK shall not make, or cause to be made, any written or oral claim that is false,
21 misleading, or deceptive about any GSK Product.

22 B. GSK shall not represent that any GSK Product has any sponsorship, approval,
23 characteristics, ingredients, uses, benefits, quantities, or qualities that it does not have.

24 C. GSK's policies and procedures shall address compensation (including through
25 salaries, bonuses, or other means) for GSK Sales and GSK Marketing. These policies
26 and procedures shall: (1) be designed to ensure that financial incentives do not
27 inappropriately motivate GSK Sales or GSK Marketing to engage in improper sales
28 Promotion, sales and marketing of GSK Products; and (2) include mechanisms, where

1 appropriate, to exclude from incentive compensation sales that may indicate Off-Label
2 Promotion of GSK Products. GSK shall make reasonable efforts in good faith to seek
3 contractual language with any third-party contractor of prescriber-facing sales
4 personnel requiring that any such personnel contracted to Promote GSK Products will
5 not be compensated based on territory/individual level sales goals. GSK represents
6 that, prior to the Effective Date, it implemented a program in the United States to
7 eliminate incentive compensation based on territory/individual level sales goals for
8 prescriber-facing sales personnel (e.g., sales representatives) and their direct
9 managers (Patient First Program). The Patient First Program is described in more
10 detail in Attachment A. GSK shall continue its Patient First Program or a substantially
11 equivalent program through March 1, 2019.

12 The following paragraphs D through F shall be effective for a period of eight
13 years from the Effective Date of this Judgment.

14 D. GSK shall not make in a Promotional context a representation or suggestion,
15 not approved or permitted for use in the labeling or under the FDCA, that a GSK
16 Product is better, more effective, useful in a broader range of conditions or patients,
17 safer, has fewer, or less incidence of, or less serious side effects or contraindications
18 than has been demonstrated by substantial evidence, or substantial clinical experience
19 (as described in paragraphs (e)(4)(ii)(b) and (c) of 21 C.F.R. § 202.1), whether or not
20 such representations are made by comparison with other drugs or treatments, and
21 whether or not such a representation or suggestion is made directly or through use of
22 published or unpublished literature, quotations, or other references.

23 E. GSK shall not Promote any GSK Product by use of Promotional Materials that:

- 24 1. contain a drug comparison that represents or suggests that a drug is
25 safer or more effective than another drug in some particular when it has
26 not been demonstrated to be safer or more effective in such particular
27 by substantial evidence or substantial clinical experience;
28

- 1 2. contain a representation or suggestion that a drug is safer than it has
2 been demonstrated to be by substantial evidence or substantial clinical
3 experience, by selective presentation of information from published
4 articles or other references that report no side effects or minimal side
5 effects with the drug or otherwise selects information from any source in
6 a way that makes a drug appear to be safer than has been
7 demonstrated;
- 8 3. present information from a study in a way that implies that the study
9 represents larger or more general experience with the drug than it
10 actually does; or
- 11 4. use statistics on numbers of patients or counts of favorable results or
12 side effects, derived from pooling data from various insignificant or
13 dissimilar studies in a way that suggests either that such statistics are
14 valid if they are not or that they are derived from large or significant
15 studies supporting favorable conclusions when such is not the case.
- 16 F. When presenting information about a clinical study regarding GSK Products in
17 any Promotional Materials, GSK shall not do any of the following for information that
18 may be material to an HCP prescribing decision:
 - 19 1. present favorable information or conclusions from a study that is
20 inadequate in design, scope, or conduct to furnish significant support for such
21 information or conclusions;
 - 22 2. use the concept of statistical significance to support a claim that
23 has not been demonstrated to have clinical significance or validity, or fails to
24 reveal the range of variations around the quoted average results; or
 - 25 3. use statistical analyses and techniques on a retrospective basis to
26 discover and cite findings not soundly supported by the study, or to suggest
27 scientific validity and rigor for data from studies the design or protocol of which
28 are not amenable to formal statistical evaluations.

Clinical Research

The following subsection shall be effective for eight years from the Effective Date of this Judgment.

G. GSK shall report research in an accurate, objective, and balanced manner as follows and as required by applicable law. To the extent permitted by the National Library of Medicine and as required by the FDA Amendments Act of 2007 (Public Law No. 110-85), GSK shall register GSK-sponsored Applicable Clinical Trials beginning after the Effective Date with the applicable registry and submit results of GSK-sponsored Applicable Clinical Trials completed after the Effective Date to the registry and results data bank as required by the FDA Amendments Act and any accompanying regulations that may be promulgated pursuant to that Act.

H. When submitting a manuscript on the results of a clinical study regarding any GSK Product for publication, GSK shall:

1. adhere to the ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications, including authorship criteria, unless the applicable journal or congress to which the publication is submitted has more stringent requirements, in which case the journal or congress criteria for authorship will be followed;
2. acknowledge GSK's role as a funding source of the study which is the subject of the manuscript; and
3. disclose any change to the plan for the statistical analysis for that clinical study if such change is inconsistent with GSK's standard operating procedure for Development, Review and Approval of Reporting and Analysis Plans. GSK's standard operating procedure for Development, Review and Approval of Reporting and Analysis Plans shall include requirements that such plans shall be consistent with the study protocol and shall be finalized before the date of final database release or interim database release (for an unblinded interim analysis).

1 I. For any GSK Product, GSK shall also post on GSK's clinical study registry any
2 observational studies or Meta-analyses conducted by GSK that are designed to inform
3 the effective, safe, and/or appropriate use of any GSK Product.

4 **Product Sampling**

5 The following subsection shall be effective for five years from the Effective Date
6 of this Judgment.

7 J. GSK shall not provide samples of GSK Products to those HCPs who are not
8 expected to prescribe the sampled GSK Products for an approved use, but who would
9 be expected to prescribe the sampled product for an Off-Label use.

10 K. If an HCP who would not be expected to prescribe the GSK Product for an
11 approved use, but who would be expected to prescribe the product for an unapproved
12 use, requests samples of that GSK Product, GSK personnel shall refer the HCP to
13 GSK Medical Affairs where the practitioner can speak directly with a GSK Medical
14 Affairs representative who will provide answers to the HCP's questions about the GSK
15 Product and GSK may provide him/her with samples only if appropriate (i.e., if the
16 HCP requests the samples for an FDA approved ("on-label") use).

17 **Reprints**

18 The following subsection shall be effective for five years from the Effective Date
19 of this Judgment.

20 L. GSK shall not disseminate information describing any Off-Label use of a GSK
21 Product, unless such information and materials are consistent with applicable FDA
22 regulations and FDA Guidances for Industry.

23 M. Reprints Containing Off-Label Information regarding a GSK Product:

- 24 1. shall be accompanied by the FDA-approved labeling for the product, or a
25 clearly and conspicuously described hyperlink that will provide the reader
26 with such information;

4 3. shall not be referred to or used in a Promotional manner.

O. Nothing in this Judgment shall preclude GSK from revising its policies and practices regarding the dissemination of Reprints Containing Off-Label Information to be consistent with applicable FDA regulations and FDA Guidances for Industry that are revised or newly issued after the Effective Date of this Judgment.

3 The following subsection shall be effective for five years from the Effective Date
4 of this Judgment.

0 1. Clinically Relevant Information is included in these materials to provide
1 scientific balance;

2 2. data in these materials are presented in an unbiased, non-Promotional
3 manner; and

4 3. these materials are clearly and conspicuously distinguishable from sales
5 aids and other Promotional Materials.

6 Nothing in this subsection shall prohibit GSK Scientifically Trained Personnel
7 from disseminating materials that are permitted to be distributed under Federal law.

1 Q. GSK Sales and GSK Marketing personnel shall not develop the medical content
2 of Clinical Responses regarding a GSK Product.

3 R. Clinical Responses regarding a GSK Product may be disseminated only by
4 GSK Scientifically Trained Personnel to HCPs, and GSK Sales and GSK Marketing
5 personnel shall not disseminate these materials to HCPs except in circumstances
6 implicating public health and safety issues. In such circumstances, GSK Sales and
7 GSK Marketing personnel may disseminate a Clinical Response directly to HCPs
8 when expressly authorized by the Health Care Compliance Officer, the Vice President
9 of Medical/Scientific Affairs responsible for the GSK Product(s) included in the Clinical
10 Response(s), and counsel from the GSK Law Department.

11 **Responses to Unsolicited Requests for Off-Label Information**

12 The following subsection shall be effective for five years from the Effective Date
13 of this Judgment.

14 S. In responding to an Unsolicited Request for Off-Label information regarding a
15 GSK Product, including any request for a specific article related to Off-Label uses,
16 GSK shall:

- 17 1. advise the requestor that the request concerns an Off-Label use; and
- 18 2. inform the requestor of the drug's FDA-approved indication(s), provide
19 labeling information and, where relevant to the Unsolicited Request,
20 provide dosage information.

21 T. If GSK elects to respond to an Unsolicited Request for Off-Label information
22 regarding a GSK Product, GSK Scientifically Trained Personnel shall provide specific,
23 accurate, objective, and scientifically-balanced responses. Any such response shall
24 not Promote a GSK Product for any Off-Label use(s).

25 U. Any written response to an Unsolicited Request for Off-Label information
26 regarding a GSK Product shall include:

- 27 1. an existing Clinical Response prepared in accordance with Section III.P-
28 R.

3 3. a report containing the results of a reasonable literature search using
4 terms from the request.

7 W. GSK Sales and GSK Marketing personnel may respond orally to an Unsolicited
8 Request for Off-Label information regarding a GSK Product only by offering to request
9 on behalf of the requester that a Clinical Response prepared in accordance with
0 Section III.P-R or other information set forth in the current section above be sent in
1 follow-up or by offering to put the requester in touch with GSK Medical Affairs. GSK
2 Non-Scientifically Trained Personnel shall not characterize, describe, identify, name,
3 or offer any opinions about or summarize any such Off-Label information.

15 The following subsection shall be effective for five years from the Effective Date
16 of this Judgment.

20 Y. GSK Medical Affairs shall manage all requests for funding related to medical
21 education grants relating to a GSK Product. Approval decisions shall be made by
22 GSK Medical Affairs, and shall be kept separate from the GSK Sales and GSK
23 Marketing organizations.

27 1. GSK Sales and GSK Marketing personnel shall not initiate, coordinate or
28 implement grant applications on behalf of any customer or HCP;

1 2. GSK Sales and GSK Marketing personnel shall not be involved in
2 selecting grantees or medical education speakers; and

3 3. GSK shall not measure or attempt to track in any way the impact of
4 grants or speaking fees on participating HCPs' subsequent prescribing
5 habits, practices or patterns.

6 AA. GSK shall not condition funding of a medical education program grant request
7 relating to a GSK Product upon the requester's selection or rejection of particular
8 speakers.

9 BB. GSK shall not suggest, control, or attempt to influence the specific topic, title,
10 content, speakers or audience for CMEs relating to a GSK Product, consistent with
11 Accreditation Council for Continuing Medical Education (ACCME) guidelines.

12 CC. GSK Sales and GSK Marketing personnel shall not approve grant requests
13 regarding a GSK Product, nor attempt to influence the awarding of grants to any
14 customers or HCPs for their prescribing habits, practices, or patterns.

15 DD. GSK shall contractually require each medical education provider to clearly and
16 conspicuously disclose to attendees of a medical education program regarding any
17 GSK Product(s) GSK's financial support of the medical education program and any
18 financial relationship with faculty and speakers at such medical education program.

19 EE. After initial delivery of a CME program regarding a GSK Product, GSK shall not
20 knowingly fund the same program, nor shall it provide additional funding for re-
21 distribution of the same program, if the program's speakers are Promoting a GSK
22 Product for Off-Label use in that program.

23 **IV. DISBURSEMENT OF PAYMENTS: PAYMENT TO THE STATES**

24 Within 30 (thirty) days of the Effective Date of this Consent Judgment, GSK
25 shall pay \$105 million to be divided and paid by GSK directly to each Attorney General
26 of the Multistate Working Group in an amount designated by and in the sole discretion
27 of the Multistate Executive Committee. The Parties acknowledge that the payment
28 described herein is not a fine or penalty, or payment in lieu thereof.

1 GSK will pay the State of Arizona \$3,140,126.12 (three million, one hundred
2 forty thousand, one hundred twenty-six dollars and twelve cents). Pursuant to A.R.S. §
3 44-1531.01, the Arizona Attorney General's Office shall deposit \$3,140,126.12 into the
4 Consumer Protection-Consumer Fraud Revolving Fund to be administered by the
5 Attorney General under the conditions and for the purposes provided by in A.R.S. §
6 44-1531.01.

7 **V. REPRESENTATIONS AND WARRANTIES**

8 A. GlaxoSmithKline acknowledges that it is a proper party to this Consent
9 Judgment. GlaxoSmithKline further warrants and represents that the individual signing
10 this Consent Judgment on behalf of GlaxoSmithKline is doing so in his or her official
11 capacity and is fully authorized by GlaxoSmithKline to enter into this Consent
12 Judgment and to legally bind GlaxoSmithKline to all of the terms and conditions of the
13 Consent Judgment.

14 B. The Attorney General warrants and represents that he is signing this Consent
15 Judgment in his official capacity, and that he is fully authorized by his State to enter
16 into this Judgment, including, but not limited to, the authority to grant the release
17 contained in Section VI of this Consent Judgment, and to legally bind his State to all of
18 the terms and conditions of this Consent Judgment.

19 **VI. RELEASE**

20 A. By execution of this Consent Judgment, the State of Arizona releases and
21 forever discharges GSK and all of its past and present, assigns, directors, divisions,
22 employees, officers, parents, predecessors, shareholders, subsidiaries, successors,
23 and transferees (collectively, the "Released Parties"), from the following: all civil
24 claims, causes of action, parens patriae claims, damages, restitution, fines, costs,
25 attorneys' fees, remedies and/or penalties that were or could have been asserted
26 against the Released Parties by the Attorney General under the Consumer Fraud Act,
27 A.R.S. § 44-1521 et seq. or any amendments thereto, or by common law claims
28 concerning unfair, deceptive, or fraudulent trade practices resulting from the Covered

1 Conduct, up to and including the Effective Date of this Consent Judgment (collectively,
2 the "Released Claims").

3 B. Notwithstanding any term of this Consent Judgment, specifically reserved and
4 excluded from the Released Claims as to any entity or person, including Released
5 Parties, are any and all of the following:

- 6 1. Any criminal liability that any person or entity, including Released
7 Parties, has or may have to the State of Arizona;
- 8 2. Any civil or administrative liability that any person or entity, including
9 Released Parties, has or may have to the State of Arizona, under any
10 statute, regulation, or rule not expressly covered by the release in
11 Section VI.A including, but not limited to, any and all of the following
12 claims:
 - 13 a. State or federal antitrust violations;
 - 14 b. Medicaid violations, including, but not limited to, federal Medicaid
15 drug rebate statute violations, Medicaid fraud or abuse, and/or
16 kickback violations related to Arizona's Medicaid program;
 - 17 c. Claims involving "best price," "average wholesale price," or
18 "wholesale acquisition cost;"
 - 19 d. State false claims violations; and
 - 20 e. Claims to enforce the terms and conditions of this Consent
21 Judgment.
- 22 3. Actions of state program payors of the State of Arizona arising from the
23 Covered Conduct, except for the release of civil penalties under the
24 Relevant State Consumer Protection Laws.
- 25 4. Any claims individual consumers have or may have under the State of
26 Arizona's consumer protection laws against any person or entity,
27 including Released Parties.
28

VII. CONFLICTS

1
2 If, subsequent to the Effective Date of this Consent Judgment, the federal
3 government or any state, or any federal or state agency, enacts or promulgates
4 legislation or regulations with respect to matters governed by this Consent Judgment
5 that creates a conflict with any provision of the Consent Judgment and GSK intends to
6 comply with the newly enacted legislation or regulation, GSK shall notify the Attorneys
7 General (or the Attorney General of the affected State) of the same. If the Attorney
8 General agrees, he shall consent to a modification of such provision of the Consent
9 Judgment to the extent necessary to eliminate such conflict. If the Attorney General
10 disagrees and the Parties are not able to resolve the disagreement, GSK shall seek a
11 modification from an appropriate court of any provision of this Consent Judgment that
12 presents a conflict with any such federal or state law or regulation. Changes in federal
13 or state laws or regulations, with respect to the matters governed by this Consent
14 Judgment, shall not be deemed to create a conflict with a provision of this Consent
15 Judgment unless GSK cannot reasonably comply with both such law or regulation and
16 the applicable provision of this Consent Judgment.

VIII. DISPUTE RESOLUTION

17
18 A. For the purposes of resolving disputes with respect to compliance with this
19 Consent Judgment, should any of the signatory Attorneys General believe that GSK
20 has violated a provision of this Consent Judgment subsequent to the Effective Date,
21 then such Attorney General shall notify GSK in writing of the specific objection, identify
22 with particularity the provisions of this Consent Judgment that the practice appears to
23 violate, and give GSK 30 days to respond to the notification.

24 B. Upon receipt of written notice from any of the Attorneys General, GSK shall
25 provide a good-faith written response to the Attorney General notification, containing
26 either a statement explaining why GSK believes it is in compliance with the Consent
27 Judgment or a detailed explanation of how the alleged violation occurred and
28 statement explaining how and when GSK intends to remedy the alleged violation.

1 C. Except as set forth in Sections VIII.E and F below, the Attorney General may
2 not take any action during the 30 day response period. Nothing shall prevent the
3 Attorney General from agreeing in writing to provide GSK with additional time beyond
4 the 30 days to respond to the notice.

5 D. The Attorney General may not take any action during which a modification
6 request is pending before a court pursuant to Section VII, except as provided for in
7 Sections VIII.E and F below.

8 E. Nothing in this Consent Judgment shall be interpreted to limit the State's Civil
9 Investigative Demand (CID) or investigative subpoena authority.

10 F. The Attorney General may assert any claim that GSK has violated this Consent
11 Judgment in a separate civil action to enforce compliance with this Consent Judgment,
12 or may seek any other relief afforded by law, but only after providing GSK an
13 opportunity to respond to the notification as described above and to remedy the
14 alleged violation within the 30 day response period as described above, or within any
15 other period as agreed to by GSK and the Attorney General; provided, however, that
16 the Attorney General may take any action if the Attorney General believes that;
17 because of the specific practice, a threat to the health or safety of the public requires
18 immediate action.

19 IX. COMPLIANCE WITH ALL LAWS

20 Except as expressly provided in this Consent Judgment, nothing in this Consent
21 Judgment shall be construed as:

- 22 1. relieving GSK of its obligation to comply with all applicable state laws,
23 regulations, or rules, or granting permission to engage in any acts or
24 practices prohibited by any law, regulation, or rule; or
- 25 2. limiting or expanding in any way any right any state represented by the
26 Multistate Working Group may otherwise have to enforce applicable
27 state law or obtain information, documents, or testimony from GSK
28 pursuant to any applicable state law, regulation, or rule, or any right GSK

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For Plaintiff, State of Arizona

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ATTACHMENT A

Employee and Executive Incentive Compensation Policies and Practices

Pursuant to its existing Patient First Program, GSK agrees that it will not provide financial reward (through compensation, including incentive compensation or otherwise) or discipline (through tangible employment action) its prescribing-customer-facing field sales professionals (pharmaceutical sales representatives) or their direct managers based upon the volume of sales of GSK Products within a given employee's own territory or the manager's district. The Patient First Program includes evaluations for sales representatives based on business acumen, customer engagement, and scientific knowledge about GSK's Products. GSK shall continue its Patient First Program, or a substantially equivalent program through March 1, 2019. GSK commits to maintaining through at least March 1, 2019, absent agreement otherwise with the Multistate Executive Committee, the restrictions on such tangible employment decisions set forth in its Use of Territory/Individual Sales Data policy.